May 12, 2022

KL-Kepong Rubber Products SDN. BHD.
% Kewin Tham
Official Correspondent
mdi Consultants, Inc.
55 Northern Blvd, Suite 200
Great Neck, New York 11021

Re: K220118
Trade/Device Name: Nitrile Powder Free Examination Gloves, Chemotherapy Nitrile Powder Free Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-powdered patient examination glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC
Dated: April 6, 2022
Received: April 11, 2022

Dear Kewin Tham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bifeng Qian, M.D., Ph.D.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220118

Device Name
Nitrile Powder Free Examination Gloves

Indications for Use *(Describe)*
A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

K220118

Date Summary Prepared: 12 May 2022

1. Submitter's Identification:

KL-KEPONG RUBBER PRODUCTS SDN. BHD.
Lot 134905, ¾ Mile Off Jalan Bercham,
Kawasan Perindustrian Bercham,
31400 Ipoh, Perak, Malaysia

Contact: Michael Ng Seng Chueng
Tel: +605-5417337

2. Name of the Devices:

Name of Device Candidate #1:
Nitrile Powder Free Examination Gloves

Name of Device Candidate #2:
Chemotherapy Nitrile Powder Free Examination Gloves

3. Regulatory Information:

For Device Candidate #1:

Regulation Name:	Polymer Patient Examination Glove
Regulatory Class:	Class I
Product Code:	LZA
Regulation Number:	21 CFR 880.6250
Panel:	General Hospital

For Device Candidate #2:

Regulation Name:	Patient Examination Glove, Specialty
Regulatory Class:	Class I
Product Code:	LZC
Regulation Number:	21 CFR 880.6250
Panel:	General Hospital

4. Predicate Device Information:

For both Device Candidate #1 and Device Candidate #2:

Predicate Device:	K182851

Trade/Device Name:	SkyBreeze Zero Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs
Device Classification Name:	Patient Examination Glove
Device Class:	Class I
Product Code:	LZA, LZC
Applicant Name:	O&M Halyard, Inc.

5. Device Description:

Two subject devices are bundled into this 510(k) submission. The subject devices, the Nitrile Powder Free Examination Gloves and the Chemotherapy Nitrile Powder Free Examination Gloves, are single use, disposable devices intended for medical purposes that are worn on the examiner's hand to prevent contamination between patient and examiner. The gloves are made of nitrile rubber, powder free, ambidextrous with beaded cuff and tested for use with chemotherapy drugs. Inner surface of gloves undergoes surface treatment process to produce a smooth surface that facilitates the user in donning the gloves without using lubricant and donning powder on the glove surface. These gloves are offered in six sizes (XS, S, M, L, XL, XXL), and supplied in non-sterile state.

The two subject devices proposed are identical in terms of sizes, materials, color, specification, and process. The only difference between the two is the chemotherapy drug labeling.

6. Indications for Use:

1. **Device Candidate #1:** Nitrile Powder Free Examination Gloves

   A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

2. **Device Candidate #2:** Chemotherapy Nitrile Powder Free Examination Gloves

   A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with the following chemotherapy drugs as per ASTM D6978-05 (2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs:

   Carmustine (BCNU) 3.3 mg/ml: no breakthrough up to 32.9 minutes
   Cisplatin 1.0mg/ml: no breakthrough up to 240 minutes
   Cyclophosphamide (Cytoxan) 20.0mg/ml: no breakthrough up to 240 minutes
   Dacarbazine 10.0mg/ml: no breakthrough up to 240 minutes
   Doxorubicin HCl 2.0mg/ml: no breakthrough up to 240 minutes
   Etoposide 20.0mg/ml: no breakthrough up to 240 minutes
   Fluorouracil 50.0mg/ml: no breakthrough up to 240 minutes
   Ifosfamide 50.0mg/ml: no breakthrough up to 240 minutes
   Methotrexate 25.0mg/ml: no breakthrough up to 240 minutes

Mitomycin C 0.5mg/ml: no breakthrough up to 240 minutes
Paclitaxel 6.0mg/ml: no breakthrough up to 240 minutes
ThioTepa 10.0mg/ml: no breakthrough up to 35.7 minutes
Vincristine Sulfate 1.0mg/ml: no breakthrough up to 240 minutes

Not recommended for use: Carmustine (BCNU) 3.3mg/ml, ThioTepa 10.0mg/ml

7. Comparison to the 510(k) Cleared Devices (Predicate Devices):

Table 1: Comparison to Predicate Device for both Device Candidate #1 and Device Candidate #2:

COMPARISON CRITERIA	Subject Device	Predicate Device (K182851)	COMPARISON RESULTS
Manufacturer	KL-Kepong Rubber Products Sdn. Bhd.	O&M Halyard, Inc.	N/A
Device Classification Name/ Regulation Number	Patient Examination Glove/ 21 CFR Part 880.6250	Patient Examination Glove/ 21 CFR Part 880.6250	Similar
Product Code	LZA, LZC	LZA, LZC	Similar
Intended Use / Indications for Use	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs as per ASTM D6978-05 (2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.	The SkyBreeze Zero Nitrile Powder-Free Exam Glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs listed on the label	Similar
Material	Nitrile	Nitrile	Similar
Powdered or powder free	Powder free	Powder free	Similar
Single use	Yes	Yes	Similar
Sterility	Non-sterile	Non-sterile	Similar
Dimensions	Meet requirements of ASTM D6319	Meet requirements of ASTM D6319	Similar
Physical properties	Meet requirements of	Meet requirements of	Similar

	ASTM D6319	ASTM D6319	
Freedom from Holes	Meet requirements of ASTM D5151	Meet requirements of ASTM D5151	Similar
Residual Powder	Meet requirements of ASTM D6124	Meet requirements of ASTM D6124	Similar
Chemotherapy Drugs Permeation Test as per ASTM D6978, minimum breakthrough detection time in minutes (for Device Candidate #2)	Meets acceptance criteria for 11 drugs	Meets acceptance criteria for 10 drugs	Minimum 9 drugs meeting acceptance criteria. Similar
	Carmustine (BCNU), 3.3 mg/ml: 32.9	Carmustine (BCNU), 3.3 mg/ml: 18.6	<240, same
	Cisplatin, 1.0mg/ml: >240	Cisplatin, 1.0mg/ml: >240	Same
	Cyclophosphamide (Cytoxan), 20.0mg/ml: >240	Cyclophosphamide (Cytoxan), 20.0mg/ml: >240	Same
	Dacarbazine, 10.0mg/ml: >240	Dacarbazine, 10.0mg/ml: >240	Same
	Doxorubicin HCl, 2.0mg/ml: >240	Doxorubicin HCl, 2.0mg/ml: >240	Same
	Etoposide, 20.0mg/ml: >240	Etoposide, 20.0mg/ml: >240	Same
	Fluorouracil, 50.0mg/ml: >240	Fluorouracil, 50.0mg/ml: >240	Same
	Ifosfamide, 50.0mg/ml: >240	Ifosfamide, 50.0mg/ml: >240	Same
	Methotrexate, 25.0mg/ml: >240	Methotrexate, 25.0mg/ml: Not tested	Additional test for subject device
	Mitomycin C, 0.5mg/ml: >240	Mitomycin C, 0.5mg/ml: Not tested	Additional test for subject device
	Paclitaxel, 6.0mg/ml: >240	Paclitaxel, 6.0mg/ml: >240	Same
	ThioTepa, 10.0mg/ml: 35.7	ThioTepa, 10.0mg/ml: 48.3	<240, same
	Vincristine Sulfate, 1.0mg/ml: >240	Vincristine Sulfate, 1.0mg/ml: >240	Same

	Mitoxantrone, 2.0mg/ml: Not tested	Mitoxantrone, 2.0mg/ml: >240	Not to be claimed
Biocompatibility ISO 10993-10 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization	Under the conditions of the study, not an irritant and not a skin sensitizer	Under the conditions of the study, not primary skin irritant; Under the conditions of the study, not a contact sensitizer	Similar
Biocompatibility ISO 10993-11 Biological Evaluation of Medical Devices- Part 11: Tests for Systemic Toxicity	Under the conditions of the study, the test article is considered non-toxic	The test article was considered non-toxic	Similar

8. <u>Summary of Non-Clinical Tests Performed for Determination of Substantial Equivalence for both Device Candidate #1 and Device Candidate #2 are as follows:</u>

Table 2: Summary Non-Clinical Tests

Standard	Testing	Requirements are met
ASTM D5151	Watertight Test (Freedom from Holes)	Pass Inspection Level G1, AQL 2.5
ASTM D6319	Dimensions	Length XS: min 220mm S: min 220mm M: min 230mm L: min 230mm XL: min 230mm XXL: min 230mm Palm Width XS: 70 ± 10mm S: 80 ± 10mm M: 95 ± 10mm L: 110 ± 10mm XL: 120 ± 10mm XXL: 130 ± 10mm Thickness Finger: min 0.05mm Palm: min 0.05mm
ASTM	Physical	Before Aging:

D6319	Properties	Tensile strength: min 14MPa Ultimate elongation: min 500% After Aging: Tensile strength: min 14MPa Ultimate elongation: min 400%
ASTM D6124	Powder Amount	Residual powder <2.0mg/glove
ASTM D6978	Chemotherapy Drugs Permeation Test	An assessment is made based on the permeation (breakthrough) of 11 chemotherapy drugs through the glove material over a certain period of time (See Table 1)

Table 3: Summary of Biocompatibility Tests

ISO 10993-10	Biological Evaluation on Medical Devices- Part 10: Test for Irritation and Skin Sensitization	Pass primary skin irritation test and dermal sensitization test
ISO 10993-11	Biological Evaluation of Medical Devices- Part 11: Tests for Systemic Toxicity	Pass systemic toxicity test

The following National and International Standards were utilized for testing the subject device:

ASTM D6319-19	Standard Specification for Nitrile Examination Gloves for Medical Application
ASTM D5151-19	Standard Test Method for detection of Holes in Medical Gloves
ASTM D6124-06	Standard Test Method for Residual Powder on Medical Gloves
ASTM D6978-05	Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
ISO 10993-10	Biological Evaluation on Medical Devices- Part 10: Test for Irritation and Skin Sensitization
ISO 10993-11	Biological Evaluation of Medical Devices- Part 11: Tests for Systemic Toxicity

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our

conclusion that Nitrile Powder Free Examination Gloves/Chemotherapy Nitrile Powder Free Examination Gloves tested met all relevant requirements of the aforementioned tests.

9. Summary of Clinical Tests Performed for both Device Candidate #1 and Device Candidate #2:

Not applicable. Clinical data is not required for marketing clearance of patient examination gloves.

10. Conclusions for both Device Candidate #1 and Device Candidate #2:

The conclusion drawn from the non-Clinical tests demonstrates that the subject devices, the Nitrile Powder Free Examination Gloves and the Chemotherapy Nitrile Powder Free Examination Gloves are as safe, as effective, and perform as well as or better than the legally marketed predicate device cleared under K182851.